



Translation

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference T760SAISEI-1	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/JP2003/011471	International filing date (day/month/year) 09 September 2003 (09.09.2003)	Priority date (day/month/year) 09 September 2002 (09.09.2002)
International Patent Classification (IPC) or national classification and IPC A61L 27/56, C12M 3/00, C12N 5/08		
Applicant KANEKA CORPORATION		

- This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 7 sheets, including this cover sheet.
- This report is also accompanied by ANNEXES, comprising:
 - ☐ (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:
 - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
- This report contains indications relating to the following items:

<input checked="" type="checkbox"/> Box No. I	Basis of the report
<input type="checkbox"/> Box No. II	Priority
<input checked="" type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/> Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/> Box No. VI	Certain documents cited
<input type="checkbox"/> Box No. VII	Certain defects in the international application
<input type="checkbox"/> Box No. VIII	Certain observations on the international application

Date of submission of the demand 17 March 2004 (17.03.2004)	Date of completion of this report 17 September 2005 (17.09.2005)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

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Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ The international application as originally filed/furnished

☐ the description:

pages _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the claims:

pages _____, as originally filed/furnished

pages* _____, as amended (together with any statement) under Article 19

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the drawings:

pages _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (*specify*): _____

☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (*specify*): _____

☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 20

because:

☒ the said international application, or the said claims Nos. 20
relate to the following subject matter which does not require an international preliminary examination (*specify*):

See supplemental sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _____.

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the
Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with
the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ see Supplemental Box for further details.

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III. 1.

The invention set forth in claim 20 is "a method for the treatment of osteoporosis", which corresponds to a method of treatment of the human body by therapy.

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	5-8, 13-15, 18, 19	YES
	Claims	1-4, 9-12, 16, 17	NO
Inventive step (IS)	Claims		YES
	Claims	1-19	NO
Industrial applicability (IA)	Claims	1-19	YES
	Claims		NO

2. Citations and explanations

Document 1: EP 1234587 A1 (Ethicon, Inc.), 28 August 2002

Document 2: WO 00/62829 A1 (Rutgers, The State
University), 26 October 2000

1. The inventions set forth in claims 1 to 4, 9 to 12, 16 and 17 lack novelty and do not involve an inventive step in the light of document 1 cited in the international search report.

Document 1 sets forth a three-dimensional porous support for tissue regeneration, wherein longitudinal pores with a diameter of 30 to 200µm (see paragraph [0012]) and a length of around 100µm (see paragraph [0016]) are positioned in parallel (see fig. 2). Document 1 also indicates that the areas between the pores have a structure linking the pores with micro-pores, and said support comprises a biologically compatible material; that a polyε-capro-lactone copolymer may be selected as a biologically compatible material; that said support is a three-dimensionally bonded cell mass which cultures cells of tissue origin cells, such as bone, joint cartilage, ligaments, tendons, or liver cells; and discloses a method for the manufacture therefor.

Therefore the inventions set forth in 1 to 4, 9 to 12, 16 and 17 are identical to the inventions set forth in document 1.

2. The inventions set forth in claims 5 to 8, 13 to 15, 18 and 19 do not involve an inventive step in the light of documents 1 to 3 cited in the international search report.

Document 2 sets forth a three-dimensional porous support body for tissue engineering, having a highly interconnected vertical distribution of pores of approximately 50 to about 500 μ m in diameter and small pores less than 20 μ m in size, wherein said support comprises a biocompatible material, and polycaprolactones may be selected as said biocompatible material. Document 2 also sets forth as a method for producing said support, a method wherein the support material is dissolved in an organic solvent, said solution is poured into a mold, and freeze-dried rapidly at a low temperature, and said freeze-dried solution is vacuum dried to remove organic solvents. Document 2 thereby sets forth a three-dimensional cell bonding structure and the method for production thereof, wherein cells of stem cell origin, or cells of tissue origin, such as bone or joint cartilage, are cultivated on said support.

The three-dimensional porous support set forth in document 1 has an extremely similar structure to the three-dimensional porous support set forth in document 2, and said biocompatible material and applicable cells are almost the same.

It would therefore be easy for a person skilled in the art to conceive of applying the method set forth in document 2 as a method for producing the three-dimensional

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porous support set forth in document 1 and to obtain a three-dimensional cell bonding structure on which cartilage of a living body is cultivated on the three-dimensional porous support obtained by said method,.

In addition, it would not be particularly difficult for a person skilled in the art to apply the stem cells set forth in document 2 as the cells applied to the three-dimensional porous support set forth in document 1.